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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/575,883

09/15/2006

Siegfried Ansorge

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EXAMINER

SZNAIDMAN, MARCOS L

ART UNIT

PAPER NUMBER

1612

NOTIFICATION DATE

DELIVERY MODE

03/05/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com  
pto@gbpatent.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/575,883	<b>Applicant(s)</b> ANSORGE ET AL.	
	<b>Examiner</b> MARCOS SZNAIDMAN	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 26 November 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 93-111 is/are pending in the application.
- 4a) Of the above claim(s) 95,98 and 100-104 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 93-94, 96-97, 99 and 105-111 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This office action is in response to applicant's reply filed on November 26, 2008.

#### ***Status of Claims***

Cancellation of claims 77-92 and addition of new claims 93-111 is acknowledged.

Claims 93-111 are currently pending and are the subject of this office action.

The following species are currently under examination: compound D3.008 (which is free of prior art), elected by applicant in the reply filed on May 13, 2008; and Lupanine (CAS # 550-90-3), selected by the Examiner as the next species examined in an expanded search in the Office Action dated August 29, 2008.

The combined set of claims that read on one or both species, and as a consequence are under examination are: 93-94, 96-97, 99 and 105-111.

Claims 95, 98, and 100-104 are withdrawn from consideration because they don't read on the elected invention and/or on any of the two species being examined.

#### ***Priority***

The present application is a 371 of PCT/EP04/11645 filed on 10/15/2004.

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English

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translation of the foreign application must be submitted in reply to this action. 37

CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

***Rejections and/or Objections and Response to Arguments***

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated (Maintained Rejections and/or Objections) or newly applied (New Rejections and/or Objections, Necessitated by Amendment or New Rejections and/or Objections not Necessitated by Amendment). They constitute the complete set presently being applied to the instant application.

***Claim Rejections - 35 USC § 112 (New Rejection Necessitated by Amendment)***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 105, 108 and 111 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 105, 108 and 111 recite a composition “which is adapted for use”.

The instant specification provides no clear definition of the phrase “which is

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adapted for use”, and since the term is appended to an otherwise already definite phrase (“pharmaceutical composition”), its modifying function is unclear.

***Claim Rejections - 35 USC § 102 (new Rejection not necessitated by  
Amendment)***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 93 is rejected under 35 U.S.C. 102(b) as being anticipated by Tobin et. al. (US 3,121,043).

Claim 93 recites a pharmaceutical or cosmetic composition comprising at least one of a pharmaceutically acceptable carrier and a pharmaceutically or cosmetically acceptable adjuvant and at least one active ingredient selected from formula D3.

For claim 93, Tobin teaches a pharmaceutical composition of lupanine (expanded species) further comprising a copolymer (a carrier) (see column 2, lines 50-61 and entire description). Tobin further teaches the use of water (an adjuvant according to the definition of adjuvant on page 16 of the specification) as a solvent (see Example II on column 8).

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***Claim Rejections - 35 USC § 103 (new Rejection not necessitated by  
Amendment)***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a

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later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 93, 105, 108 and 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tobin et. al. (US 3,121,043) in view of Oettel et. al. (US 2002/0065260).

Claim 93, 105, 108 and 111 recite a pharmaceutical or cosmetic composition comprising at least one of a pharmaceutically acceptable carrier and a pharmaceutically or cosmetically acceptable adjuvant and at least one active ingredient selected from formula D3.

For claims 93, 105, 108, and 111 Tobin teaches a pharmaceutical composition of lupanine (expanded species) further comprising a copolymer (a carrier) (see column 2, lines 50-61 and entire description).

Tobin does not teach a pharmaceutically or cosmetically acceptable adjuvant. However, Oettel teaches that adjuvants are common use in the pharmaceutical industry (see paragraph [0043], lines 10 and 11).

At the time of the invention, it would have been *prima facie* obvious for the skilled artisan to have a pharmaceutical composition of lupanine and a pharmaceutically acceptable carrier as taught by Tobin and further add an adjuvant as taught by Oettel, with the motivation of obtaining a better formulation of lupanine, thus resulting in the practice of claims 93, 105, 108 and 111 with a reasonable expectation of success.

The statement in claim 93: “a pharmaceutical or cosmetic” is considered an intended use and does not add any new limitation to the claim. *Catalina Mktg. Int’l, Inc. V. Coolsavings.com, Inc.*, 289 F.3d 801, 808, 62 USPQ2d 1781, 1785 (fed. Cir. 2002). “The recitation of a new intended use for an old product does not make a claim to that old product patentable.” *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997).

***Claim Rejections - 35 USC § 103 (new Rejection necessitated by  
Amendment)***

Claim 106 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tobin et. al. (US 3,121,043) in view of Oettel et. al. (US 2002/0065260) as applied to claims 93, 105, 108 and 111 above, and further in view of Ding et. al. (US 6,120,536).

Claim 106 further limits claim 93, wherein the composition is comprised in a coating of a stent.

Tobin and Oettel teach all the limitations of claim 106, except for the composition being comprised in a coating of a stent. However, Ding teaches that coating stents with pharmaceutical agents is common practice in the pharmaceutical industry (see column 1, last paragraph and column 2, first and second paragraphs).

At the time of the invention, it would have been *prima facie* obvious for the skilled artisan to have the pharmaceutical composition of claim 93 comprised in a coating of a stent as taught by Ding, with the motivation of having a better



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delivery of the active ingredient (lupanine), Thus resulting in the practice of claim 106 with a reasonable expectation of success.

Claims 107 and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tobin et. al. (US 3,121,043) in view of Oettel et. al. (US 2002/0065260) as applied to claim 93 above, and further in view of Papathanassiu (US 6,528,489).

Claim 107 further limits claim 93, wherein the composition is suitable for topical administration.

Tobin and Oettel teach all the limitations of claim 107, except for being suitable for topical administration. However, Papathanassiu teaches that topical administration of active ingredients are common practice in the pharmaceutical industry (see column 5, second paragraph).

At the time of the invention, it would have been *prima facie* obvious for the skilled artisan to have the pharmaceutical composition of claim 93 suitable for topical administration as taught by Papathanassiu, with the motivation of having a better form of administration, thus resulting in the practice of claim 107 with a reasonable expectation of success.

Claim 109 further limits claim 93, wherein the composition is present as a cream an ointment, a paste, and a gel.

Tobin and Oettel teach all the limitations of claim 109, except for the composition being a cream, an ointment, a paste or a gel. However,

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Papathanassiu teaches that creams, ointments, pastes and gels are common formulations of active ingredients in the pharmaceutical industry (see column 5, second paragraph).

At the time of the invention, it would have been *prima facie* obvious for the skilled artisan to have the pharmaceutical composition of claim 93 in a form of a cream, ointment, past or gel as taught by Papathanassiu, with the motivation of having a better formulation for the active ingredient, thus resulting in the practice of claim 109 with a reasonable expectation of success..

Claim 110 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tobin et. al. (US 3,121,043) in view of Oettel et. al. (US 2002/0065260) as applied to claim 93 above, and further in view of Lintner (US 6,620,419).

Claim 110 further limits claim 93, wherein the composition is present in combination with at least one of a depot matrix, a hydrocolloid dressing, a plaster, a micro-sponge and a prepolymer.

Tobin and Oettel teach all the limitations of claim 110, except for being present in combination with at least one of a depot matrix, a hydrocolloid dressing, a plaster, a micro-sponge and a prepolymer. However, Lintner teaches that micro-sponges are common use in the pharmaceutical industry (see column 6, line 44).

At the time of the invention, it would have been *prima facie* obvious for the skilled artisan to have the pharmaceutical composition of claim 93 present in a micro-sponge as taught by Lintner, with the motivation of better delivering the

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active ingredient, thus resulting in the practice of claim 110 with a reasonable expectation of success.

***Double Patenting (Maintained Rejections)***

1) Claims 93-94, 96-97, 99 and 105-111 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 78-79 of copending Application No. 10/575,878 for the same reasons that now cancelled claims 77-78 were rejected in the previous office action.

The reasons for this rejection have been provided in the previous office action dated August 29, 2008, the text of which is incorporated by reference herein.

Applicant's arguments have been fully considered but are not persuasive.

This rejection is maintained since applicant has (effectively) not responded to the rejection in a substantive manner. See 37 CFR § 1.111(b) and MPEP § 714.02.

2) Claims 93-94, 96-97, 99 and 105-111 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 77-78 of copending Application No. 10/575,882 for the

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same reasons that now cancelled claims 77-78 were rejected in the previous office action.

The reasons for this rejection have been provided in the previous office action dated August 29, 2008, the text of which is incorporated by reference herein.

Applicant's arguments have been fully considered but are not persuasive.

This rejection is maintained since applicant has (effectively) not responded to the rejection in a substantive manner. See 37 CFR § 1.111(b) and MPEP § 714.02.

***Withdrawn Rejections and/or Objections***

***Claims rejected under 35 USC 112, first paragraph (written description).***

Due to applicant's cancellation of claims 77-78 and addition of new claims 93-94, 96-97, 99 and 105-111, the written description rejection is now moot.

Rejection under 35 USC 112, first paragraph (written description) is withdrawn.

***Claims rejected under 35 USC 103(a).***

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Applicant's arguments have been fully considered and they are persuasive.

Rejection under 35 USC 103(a) is withdrawn. However, a new rejection under 35 USC 103, not necessitated by amendment (see above) was applied.

### ***Conclusion***

No claims are allowed.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/  
Examiner, Art Unit 1612  
February 10, 2009

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612